Health Canada Santé Canada

Your health and safety... our priority. *Votre santé et votre sécurité... notre priorité.*

Re-evaluation Note REV2014-03

Special Review of Imazapyr: Proposed Decision for Consultation

(publié aussi en français)

28 August 2014

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

ISSN: 1925-0630 (print)
1925-0649 (online)

Catalogue number: H113-5/2014-3E (print version)
H113-5/2014-3E-PDF (PDF version)

© Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2014

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

1.0 Introduction

Pursuant to subsection 17(2) of the *Pest Control Products Act*, the Pest Management Regulatory Agency (PMRA) initiated a special review of pest control products containing imazapyr based on the Norwegian decision (2001) to prohibit the use in Norway.[1] The initiation of the special review of imazapyr was announced in December 2013.[2]

Pursuant to subsection 18(4) of the *Pest Control Products Act*, the PMRA has evaluated the aspect of concern that prompted the special review of imazapyr. The aspect of concern is relevant to the environment and was identified as the potential for imazapyr to leach to groundwater.

2.0 Uses of Imazapyr in Canada

Imazapyr is a herbicide, first registered in Canada in 1994. Imazapyr is currently registered for use in Canada for the control of annual and perennial grasses, broadleaf weeds and select perennial shrubs and trees on non-crop, non-graze areas. It is also registered for the control of grassy and broadleaf weeds in Clearfield canola, Clearfield canola quality *Brassica juncea* and Clearfield lentils in the Prairie provinces only. Imazapyr is applied once per year using ground spray or hand-held equipment at an application rate of 9 g a.i./ha on Clearfield canola, Clearfield canola quality *Brassica juncea* and Clearfield lentils and 720 g a.i./ha on non-crop, non-graze areas.

In Canada, imazapyr underwent re-evaluation[3] in 2008. The re-evaluation included an assessment of the risks to human health and the environment from all uses of imazapyr registered in Canada at the time (that is, use on non-crop, non-graze areas). Subsequently, in 2011, the PMRA assessed imazapyr for use on canola, canola quality *Brassica juncea* and lentils.[4]

Appendix I lists all imazapyr products that are currently registered under the authority of the *Pest Control Products Act*. The technical active ingredient, manufacturing concentrates and all end-use products containing imazapyr are considered in this review. The proposed special review decision is applicable for all registered products containing imazapyr.

---

1 Rotterdam Convention, 2001. Secretariat for the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, PIC Circular XIV – December 2001.

2 Canada, 2013. Pest Management Regulatory Agency Regulatory Note REV2013-06, *Special Review Initiation of 23 Active Ingredients*.

3 Canada, 2008a. Pest Management Regulatory Agency Proposed Re-evaluation Decision PRVD2008-10, *Imazapyr* and; Canada, 2008b. Pest Management Regulatory Agency Re-evaluation Decision RVD2008-17, *Imazapyr*.

4 Canada, 2011. Pest Management Regulatory Agency Proposed Registration Decision PRD2011-12, *Imazapyr* and; Canada, 2012. Pest Management Regulatory Agency Registration Decision RD2012-10, *Imazapyr*.

3.0 Aspect of the Pest Control Product that Prompted the Special Review

The use of imazapyr as a pesticide in Norway was banned in 2001 due to environmental concerns. The Norwegian assessment concluded that imazapyr was mobile and persistent in soil, and may reach groundwater in concentrations above the Norwegian limit of 0.1 µg/L for pesticide in groundwater.[5] The expected effect of the regulatory action was identified in the Rotterdam Convention PIC Circular XIV as "reducing the risk for groundwater contamination."[6] The reasons for the Norwegian regulatory action, as outlined in the PIC Circular, were summarised as follows:

"Arsenal 250 was denied re-registration due to unacceptable risk for groundwater contamination, caused by high mobility and persistence in soil."

Based on the review of the Norwegian decision, the PMRA has identified the aspect of concern that prompted the special review of imazapyr as the potential for imazapyr to leach to groundwater.

4.0 PMRA Evaluation of the Aspect of the Pest Control Product that Prompted the Special Review

Following the initiation of the special review of imazapyr, the PMRA requested information from provinces and other relevant federal departments and agencies, in accordance with subsection 18(2) of the *Pest Control Products Act*.

In order to evaluate imazapyr's potential for leaching to groundwater, the PMRA has considered currently available relevant scientific information, which includes information considered for the re-evaluation[7] of imazapyr, the recent registration[8] of products containing imazapyr in Canada, and any relevant information obtained since then (for example, environmental fate information from laboratory and field studies, available Canadian and American groundwater monitoring data, groundwater modelling, information from the Canadian incident report database).

---

5 Norway, 2001. Form for Notification of Final Regulatory Action to Ban or Severely Restrict a Chemical. Imazapyr. Norwegian Agricultural Inspection Service.

6 Rotterdam Convention, 2001. Secretariat for the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, PIC Circular XIV – December 2001.

7 Canada, 2008a. Pest Management Regulatory Agency Proposed Re-evaluation Decision PRVD2008-10, *Imazapyr* and; Canada, 2008b. Pest Management Regulatory Agency Re-evaluation Decision RVD2008-17, *Imazapyr*.

8 Canada, 2012. Pest Management Regulatory Agency Registration Decision RD2012-10, *Imazapyr*.

Imazapyr is soluble in water (water solubility of 9.74 g/L at 15°C and 11.3 g/L at 25°C). Imazapyr is not expected to volatilize from moist soils or water surfaces. It is also not expected to bioaccumulate. Imazapyr hydrolyzes slowly in water and phototransformation in soil is not considered an important route of transformation. Imazapyr is stable to biotransformation in soil (aerobic soil half-life is >296 days and DT_{50} value greater than 60 days in anaerobic soil) and in aerobic and anaerobic lake/water sediment systems. Based on imazapyr's organic carbon partition coefficient (K_{oc} values of 63-700) from laboratory studies, imazapyr has potential for mobility in soil.

In addition to the laboratory studies, several field studies of dissipation in Canada and the United States were also considered to assess the leaching potential of imazapyr. In terrestrial field trials conducted in Alberta, at an application rate similar to the highest Canadian application rate, imazapyr dissipated to below the level of detection within two months and was not found below 10 cm. In addition, American field studies in Canadian relevant ecozones have demonstrated half-lives between 94 and 143 days. In four field trials in the northern United States, imazapyr had dissipated to concentrations below the level of detection within six months. In these field studies, imazapyr residues were restricted mainly to the top 15 cm of soil, with trace amounts being found between 15 and 30 cm. In a New Jersey (United States) field study, in which plants were treated with ^{14}C-imazapyr, imazapyr persisted in the plants, and was added to the soil when the plants died; radioactive residues were found to a depth of 53 cm below the soil surface.

Overall, the field studies indicated that imazapyr is detected in the 0-55 cm soil layer and the dissipation half-lives were less than the laboratory studies of persistence.

The potential for groundwater leaching under Canadian use conditions was assessed using modelling. The potential for imazapyr to leach to groundwater was assessed using the Leaching Estimation and Chemistry Model (LEACHM). Estimated Environmental Concentrations of imazapyr in groundwater were based on the maximum yearly application rate of imazapyr on currently registered food crops (9 g a.i./ha). The maximum estimated environmental concentration calculated for imazapyr groundwater was 2.0 µg a.i./L. In addition, estimated drinking water concentrations for imazapyr in groundwater calculated using the SCI-GROW model based on a single application at 1.69 kg a.i./ha (approximately two times the maximum Canadian application rate), were considered. The maximum estimated drinking water concentration calculated for imazapyr in groundwater was 36 µg a.i./L

Available groundwater monitoring data from Canada and the United States were also considered. No Canadian groundwater monitoring data on imazapyr are available; however, American monitoring data are available from the State of Montana and the United States Department of Agriculture's Pesticide Data Program. Imazapyr was detected above the level of quantification in less than 10% of the 970 samples collected in groundwater from the State of Montana. The maximum detection of imazapyr relevant to the use pattern was 11 µg/L. Imazapyr was detected in 8% of the 1654 groundwater samples collected as part of the United States Department of Agriculture's Pesticide Data Program. The maximum detection of imazapyr was 3.054 µg/L.

No additional relevant information related to the aspect of concern of imazapyr was submitted to the PMRA, nor were any relevant incident reports in the Canadian database.

5.0 Drinking Water Risk Assessment

In addition to reviewing the potential for imazapyr to reach groundwater from pest control products containing this active ingredient, the PMRA has conducted a scientifically based drinking water risk assessment to determine whether exposure to imazapyr through Canadian groundwater presents an unacceptable risk to Canadians. The maximum estimated levels of imazapyr in groundwater under current conditions of use were incorporated into the dietary risk assessment to assess the potential risk from exposure through drinking water.

For assessing risks from potential residues, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects to take into account completeness of the data with respect to the exposure of, and toxicity to, infants and children, and potential prenatal and postnatal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data. The *Pest Control Products Act* factor was reduced from 10-fold to 1-fold for imazapyr because the toxicity database, as it pertains to the toxicity to infants and children, is complete, and there is no indication of increased susceptibility of fetuses or offspring compared to parental animals in reproductive and developmental studies.

The drinking water risk assessment is based on an acceptable daily intake of 2.53 mg/kg bw/day, which was derived using a no observed adverse effects level of 253 mg/kg bw/day from a 24-month rat combined chronic/carcinogenicity study and a composite assessment factor of 100 (10-fold for interspecies extrapolation, 10-fold for intraspecies variability, 1-fold *Pest Control Products Act* factor). An acute reference dose was not established as there were no acute endpoints of concern in the imazapyr database. A cancer endpoint was also not identified for imazapyr.

Dietary exposure from food and water, when assessed using the estimated groundwater concentration specific to imazapyr food-crop uses in Canada (2.0 µg a.i./L, calculated using the LEACHM model and an application rate of 9 g a.i./ha), indicated that imazapyr exposure by this route was minimal for all population subgroups. In addition, as part of the drinking water risk assessment, the PMRA considered the highest drinking water concentrations estimated from groundwater and surface water modelling. Chronic dietary exposure was not of concern (less than 0.1% of the acceptable daily intake for all population subgroups) when using the highest estimated imazapyr drinking water concentration of 79 µg a.i./L (estimated for surface water with an application rate of 1.69 kg a.i./ha [approximately two times the maximum Canadian application rate]). Furthermore, chronic dietary exposure is not expected to be of concern based on levels of imazapyr detected in the currently available American groundwater monitoring data.

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources as well as from all known or plausible exposure routes (oral, dermal and inhalation). For imazapyr, aggregate exposure is limited to food and drinking water only. As described above, aggregate exposure to food and drinking water is not of concern for imazapyr (less than 0.1% of the acceptable daily intake for all population subgroups).

A common mechanism of toxicity has not been identified for imazapyr and other active ingredients. Therefore, a cumulative risk assessment is not required for imazapyr.

The Norwegian *Drinking Water Regulations* (Regulation No. 1372) set quality standards for drinking water in Norway including a threshold of 0.1 µg/L for any individual pesticide in water intended for human consumption. The 0.1 µg/L threshold is a legislated, rather than risk-based value that applies to all pesticides regardless of their toxicity to humans. The PMRA follows a risk-based scientific approach in determining the risk to human health from pesticides in drinking water. This approach takes into consideration both the estimated level in drinking water sources and the toxicity of the pesticide. Based on the drinking water risk assessment of imazapyr, the PMRA concludes that there are no chronic risks of concern from groundwater under the current conditions of use, and therefore, no additional risk mitigation measures are required. However, advisory environmental hazard statements to reduce the potential leaching of imazapyr to groundwater are proposed for all registered pest control products containing imazapyr to meet the current labelling standard (Appendix II).

6.0 Proposed Special Review Decision for Imazapyr

Evaluation of available relevant scientific information related to the aspect of concern, in other words, the potential of imazapyr to leach into groundwater, indicates that imazapyr does not pose unacceptable risks to human health or the environment, taking into account current conditions of use. On this basis, the PMRA, under the authority of the *Pest Control Products Act*, is proposing to confirm the current registration of imazapyr products for sale and use in Canada with the proposed label amendments.

This proposed special review decision is a consultation document.[9] The PMRA will accept written comments on this proposal up to 60 days from the date of publication of this document. Please forward all comments to Publications (please see contact information on the cover page of this document).

7.0 Next Steps

Before making a special review decision on imazapyr, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a special review decision document, which will include the decision, the reasons for it, a summary of the comments received on the proposed decision and the PMRA's response to these comments.

[9] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

Appendix I Registered Products Containing Imazapyr as of 6 May 2014

Registration Number	Marketing Class	Registrant	Product Name
23712	Technical	BASF Canada Inc.	IMAZAPYR TECHNICAL HERBICIDE
23713	Commercial	BASF Canada Inc.	ARSENAL HERBICIDE
29294	Manufacturing concentrate	BASF Canada Inc.	ARSENAL BULK HERBICIDE
30188	Commercial	BASF Canada Inc.	ARES
30203	Commercial	BASF Canada Inc.	ARSENAL POWERLINE HERBICIDE
30506	Manufacturing concentrate	BASF Canada Inc.	ARES BULK HERBICIDE

Appendix II – Proposed Label Amendments for Imazapyr

1. The label of imazapyr end-use products must be amended to include the following statements.

   Add to ENVIRONMENTAL HAZARDS:

   > This product demonstrates the properties and characteristics associated with chemicals detected in ground water. The use of [product name] in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination.

References

Published Information

PMRA Document Number	Reference
1560208	Canada, 2008a. Pest Management Regulatory Agency Proposed Re-evaluation Decision PRVD2008-10, Imazapyr.
1626486	Canada, 2008b. Pest Management Regulatory Agency Re-evaluation Decision RVD2008-17, Imazapyr.
2098183	Canada, 2011. Pest Management Regulatory Agency Proposed Registration Decision PRD2011-12, Imazapyr.
2177561	Canada, 2012. Pest Management Regulatory Agency Registration Decision RD2012-10, Imazapyr.
2405939	Canada, 2013. Pest Management Regulatory Agency Regulatory Note REV2013-06, Special Review Initiation of 23 Active Ingredients.
2418424	Rotterdam Convention, 2001. Secretariat for the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, PIC Circular XIV – December 2001, DACO: 12.5.
1774484	United States Department of Agriculture. 2008. Pesticide Data Program Annual Summary. Calendar Year 2007. DACO 8.6.
1852614	United States Department of Agriculture. 2009. Pesticide Data Program. Annual Summary, Calendar Year 2008. DACO 8.6.
2312776	United States Department of Agriculture. 2011. Pesticide Data Program. Annual Summary, Calendar Year 2009. DACO 8.6.
2312778	United States Department of Agriculture. 2012. Pesticide Data Program. Annual Summary, Calendar Year 2010. DACO 8.6.
2312780	United States Department of Agriculture. 2013. Pesticide Data Program. Annual Summary, Calendar Year 2011. DACO 8.6.

Unpublished Information

PMRA Document Number	Reference
2404790	Montana Department of Agriculture. 2014. Monitoring data from the Montana Department of Agriculture. DACO 8.6.
2418435	Norway, 2001. Form for Notification of Final Regulatory Action to Ban or Severely Restrict a Chemical. Imazapyr. Norwegian Agricultural Inspection Service.